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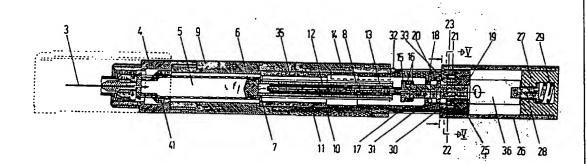
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(54) Title: INJECTION PEN



(57) Abstract

In an injection pen with a piston rod constructed as a piece (12) being able to be displaced axially in a pen case (9, 17, 35), this piece (12) having screwed into it a screw piece (13), the preadjustment of the movement of the piston can take place by means of a turn of the screw piece (13). In such a pen a slide coupling (16) on the screw piece (13) will mean that an ampoule (5, 41) is easily inserted by being pressed in from the end of the case as this will enable the screw piece (13) to turn without trouble and in this way shorten the piston rod to its starting position. Furthermore, electrical contacts (30, 31, 32, 33) have been built into the pen for supervision or control of the position of the individual parts which contacts are connected to an electronic control unit (10) as well as a display (11) for visual supervision or control and showing of the injected amount (40) of liquid, the remaining amount (38) in the ampoule (5), the adjusted amount of liquid and time elapsed since the preceding or last injection.

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INJECTION PEN

The present invention relates to an injection comprising a case in which an ampoule for a liquid can be inserted and from which liquid is given-off through a tube in the form of a hypodermic needle by pressing a piston downwards within the ampoule by means of a motive device comprising a piston rod that is able to be moved axially and consisting of an outer piece which can be displaced axially in the case and is provided internally with a thread into which a screw is screwed, which screw at the end facing away from the piston is provided with a fixed flange with a pin which by turning can preadjust the length of the piston rod and consequently the axial movement of the piston for giving-off a definite amount of liquid, and where the pin is provided with a stopring cooperating with a fixed stop-face placed in the case for the limitation of the pressing-in movement of the piston rod.

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Injection pens of this kind or type are used in particular by diabetics who have a need for injections of intermediary human insulin being dosed normally once or twice a day or human insulin in a standard mixture being dosed in order to control a postprandial rise in the blood sugar.

In order to be able to dose with the desired exactness it is possible prior to the injection to adjust the pen to giving-off the number of insulin units for which there is a need. After this the injection takes place by either screwing or pressing a piston rod down against a piston present in the ampoule in such a way that the piston is being moved corresponding exactly to the predetermined dose.

When the ampoule has been emptied it can be removed from the case and a filled ampoule can be inserted.

This requires that the piston is moved back in order to make room for the ampoule in the case. Where cooperating piston rods are used this moving back takes place by turning one of the rods back in order to screw the rods together to bring about the necessary shortening. After this the ampoule can be inserted and the pen again be made ready for injecting.

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This screwing together is hard and time-comsuming, and it also requires a certain deftness and some care so that it can be made sure that the piston rod has been moved all the way back to its initial or starting position.

In order to avoid the screwing back there can be used mechanical disconnection of the means of propulsion actuating the piston. However, these means also require a certain deftness as a person working the pen either has to work the part of the piston rod projecting down below the case when the case has been taken apart for changing the ampoule or has to disconnect the control part being used for adjusting the doses.

In this case a disconnection can take place by turning the parts with respect to each other whereby a thread engagement can be disengaged or a person working the the pen can - by means of a partial displacement of for example the adjustment part or the pressing part with respect to the piston rod - disconnect the connection.

After moving the piston rod back to the initial position 35 an ampoule can be inserted. After this the driving mechanism for the piston rod has to be connected again and this renewed connection takes place by pushing the parts together or by turning the parts together, whereafter the pen is ready for use.

It is the object of the invention to remedy these deficiencies and disadvantages related to the injection pens of the prior art, and this object is achieved by a pen, characterized in that a slide coupling is placed on a pin between a flange and a stop-face.

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By this a substatial simplification of the working of the pen is achieved since the piston rod can be screwed together simply by pressing the ampoule and the piston into the case towards the lower end of the piston rod.

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The screw and the pin are hereby brought to turn and by this the screw screws itself down into the outer part of the piston rod which outer part of the rod is mounted in such a way that it is able to be displaced axially but not able to turn so that the piston rod is shortened concurrently with the pushing-in of the ampoule into the case.

The slide coupling has the effect that the screwing together can take place at a low friction so that the ampoule during the insertion into the case merely has to be subjected to slight pressure.

When the ampoule has been inserted completely the piston rod has at the same time been moved back into its intial position and after this the piston rod is ready to be preadjusted by being elongated the desired length by turning the pin. Because the piston rod always bears against the piston there is no need for any form of preadjustment to protect against clearance between the piston rod and the piston.

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Hereby a manual screwing together or disconnection/connection of the motive device is avoided.

The guarantee that the pen functions correctly has therewith been increased as the location of the ampoule in the case is exactly determined by an accurate adaption of its room and as a consequence of its location in the case. Simultaneously with this there is achieved a guarantee that there is always direct contact between piston and piston rod whereby an exact dosage is dependent only on the elongation of the piston rod which elongation is achieved solely by turning the pin.

By, as dealt with in claim 2, providing the rearmost part of the pin with a drum which can be worked from the outside it will be possible in a convenient way to turn the pin the desired length for preadjustment of the increase of the length of the piston and as a consequence of the dose.

By, as dealt with in claim 3, placing the drum in a jacket which can be displaced axially with respect to the case the movement of the piston will be able to take place by pressing the jacket in and against the case and therewith against the pin and the piston rod.

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By, as dealt with in claim 4, having the possibility of displacing the drum in the jacket the drum can optional
ly be brought into or out of turning engagement with the pin whereby the pushing together by means of the ampoule during its pressing-in is made possible.

By, as dealt with in claim 5, providing the drum and the case with means for indicating the turning movement of the drum, the person working the pen can perceive the

number of dose steps in the fingers and as a consequence in a controlled manner adjust the amount of liquid which is later to be injected.

By, as dealt with in claim 6, building-in electrical contacts and sensors at the movable parts a reliable electrical control of the positions and movements of the parts can be achieved whereby a hitherto unknown degree of control of the treatment programme can be achieved.

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By, as dealt with in claim 7, providing the drum with a number of evenly distributed projections and the sensor with an arm projecting into the path of movement of the projections the preadjustment can be detected and/or registered in an electric way.

Finally it is expedient, as dealt with in claim 8, to provide the pen with an electrical control unit and a display since by this the functions of the pen can be visualized in the display.

In the following the invention will be described in further detail with reference to the drawing, where

- 25 fig. 1 shows a longitudinal section through a pen during insertion of an ampoule,
 - fig. 2 shows the pen after the insertion of the ampoule,

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- fig. 3 shows the pen during preadjustment of the desired amount of liquid,
- fig. 4 shows the pen after the injection,

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fig. 5 shows the drum and the means of control seen

in the direction V-V in figs. 3 and 6,

fig. 6 shows the location of the electrical contacts and sensors in the case,

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- fig. 7 shows the electrical components from a different direction,
- fig. 8 shows a block diagram of the electrical parts of the pen,
 - fig. 9 shows the individual markings of the display, and
- 15 fig. 10 17 show examples of markings related to different states and positions.

In the drawing is shown an example of an embodiment of the injection pen according to the invention.

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As shown in figs. 1-4 the pen is constructed of components for the formation of a slender and easy to handle pen which without trouble can be brought along everywhere and be available when the user might so wish.

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At one end of the pen a cap 1 has been put on which in a generally known manner can be provided with a suspension clip.

The cap 1 can be taken off the rest of the case and by this there is given access to the unit 3 containing a tube in the form of a hypodermic needle which unit is protruding and is provided with a protective cap 2. The protective cap 2 is used when the unit 3 containing a tube in the form of a hypodermic needle is to be screwed into and secured in a jacket 41 at the end of an ampoule

5 for liquid in such a way that the rearmost end of the tube in the form of hypodermic needle can pass through a rubber membrane in the ampoule 5.

The liquid in the ampoule can be conducted out through the tube in the form of a hypodermic needle by injection, and after this the tube in the form of a hypodermic needle is screwed out from the membrane which guarantees that there is always ejected or extruded mixed insulin through the tube in the form of a hypodermic needle.

The ampoule 5 is at its opposite end provided with a piston 6 in such a way that movement of the piston to the left in the drawing will eject liquid through the tube in the form of a needle 3.

The ampoule 5 is placed in the central or middle piece of the case 9 in which an inner piece 35 has furthermore been inserted and at the end a guide piece 17 is inserted. Together with the in-between piece 4 these parts make up the entire case.

Besides the ampoule 5, the piston rod mechanism proper and the pushing-in mechanism have been built into this case.

The piston rod comprises an outer part 12 which is provided externally with guide grooves or slots 8 having an axial course in which guide grooves or slots 8 guide pins 7 projecting inward from the inner piece 35 engage. The piece 12 can hereby be displaced solely in the axial direction and is prevented from turning around its longitudinal axis.

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Internally in the rearmost part of the piece 12 there is

a thread into which the screw part 13 can be screwed. The thread has a relatively high pitch and it is therefore not self-blocking.

As it appears from the drawing the parts 12, 13 have approximately the same length and by this the building length of the pen becomes the least possible in relation to the capacity that is determined by the travel of the piston in the ampoule.

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The outer piece 12 fits the internal opening of the ampoule 5 so that it can bear against the piston 6.

In the opposite free end of the screw part 13 is mounted an end flange 15 by means of a snap lock as the screw part 13 is slitted at the end so that the turning pin 19 can be pushed in on the screw part and be locked fixedly to the screw part by means of a click assembly.

The pin 19 is fixedly connected to the screw part 13 so that a turning of one of the parts means that both parts are turned.

The pin 19 is made angular at its free end, e.g. as shown in fig. 5 with a hexagonal cross-sectional shape, out of regard for working engagement - to be mentioned later - with a turning drum.

Furthermore, on the pin 19 there is attached a a stop-30 ring 20, and in the guide piece 17 there is a cooperating end stop 18 whereas the stop-ring 20 can bear against for limitation in its forward movement during the injection.

35 Between the end flange 15 and this end stop 18 a slide coupling 16 in the form of two slide rings having a low

coefficient of friction and with an intervening slide ring is inserted on the pin 19. This serves the purpose of reducing the friction between the parts when the piston rod 12, 13 with the flange 15 is pressed in and against the stop-face 18 during the screwing together when the ampoule 5 is being inserted.

Finally on the guide piece 17 a jacket 26 is mounted which jacket can be pulled out slidingly in a groove between a pulled-out position in which position it bears against the end of the middle piece as shown in figs. 2 and 4 and a pressed-in position as shown in figs. 1 and 3.

In the end of the jacket there has been inserted a bottom piece 27 having a pin 28 that is being pressed forwards by means of a spring 29 and where the pin 28 protrudes in order to act upon the pin 19 during the pressing-in of the jacket during the injection.

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The jacket 26 is flattened on two opposite sides as indicated in fig. 5 and is in these places moreover provided with openings 36 as it appears from figs. 1 and 3.

Within the jacket a drum 25 of cylindrical shape is arranged which drum is provided with external grooves in order to facilitate the turning with the fingers as indicated in fig. 5. The outer portion of the drum projects out through the openings 36.

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At the front of the drum 25 there is mounted a ring of contact 22 and a hole is provided which has an axial course and whose cross-sectional shape corresponds to that of the pin 19 and in which the pin 19 can be inserted and secured in a mechanical connection that is fixed with respect to turning.

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Moreover, in the end of the guide piece 17 there is also worked out a circular opening into which the ring of contact 22 can be pressed when the drum 25 has been inserted in its position for being operated.

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On the outside of the ring of contact 22 there is a number of projections 23, see in particular fig. 5, which projections can slide over tooth-like projections 21 internally in the opening of the guide piece.

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By working out the teeth 21 with a suitable mutual distance it will be possible to divide the turns of the drum into steps so that a definite angular motion is being divided into jumps which can be perceived in the form of resistance between each step. By simultanenously knowing the pitch of the thread in the piston rod 12, 13 it will be possible to perform these steps so that the turning can determine the degree of dosage and thus the number of injected units.

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Furthermore, in the case there is built in a number of contacts and sensors which subsequently will be mentioned having reference to figs. 3-7.

25 For the supervision or control of the jacket 26 a contact or sensor 32 has been built into the guide piece 17 at the end of the slide path of the jacket. By means of this it can detect when the jacket has been pulled out or pressed in.

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Furthermore, two contacts or sensors 30, 33 are provided in the guide piece 17 at the end of the opening for the ring of contact 22.

35 One of the contacts 30 registers the end face of the ring of contact 22 so that electric contact is obtained

when the ring 22 bears against the contact 30 and so that it is disconnected when the parts are taken apart as shown in fig. 1.

Instead of being placed at the end face of the ring of contact 22 as shown in the drawing the contact 30 may be placed at the end of the inner piece 35 so that the contact is being acted upon when the ampoule 5 has been inserted and bears against the contact.

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The other contact 33 is, as it appears from fig. 6, a toggle contact having an arm of contact 34 that can be acted upon by the cams 23, 24 of the ring of contact 22 when the drum 25 is being turned.

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As it appears from fig. 5 the end face of the ring is provided with cams 23, 24 arranged in a circular form and with a uniform mutual distance and protruding and acting upon the arm of contact 34 in a sidewards direction. This sensor 33 thus detects the number of turning steps to which the drum 25 is being actuated. It is noted that the sensor can register a turning movement in both directions.

Finally, a contact 31 has been placed in the guide piece 17 at the stop-face 18 for the registration of the stop-ring 20 when it bears against the stop face or when the forward movement of the pin during the injection has come to an end.

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Instead of this construction the contacts 33, 34 and the contact giver 22 with the cams 23, 24 can be substituted by a not shown contact giver consisting af two conductive rings of contact mounted in the guide piece 17 between the teeth 21 and being insulated electrically from each other since the teeth are placed between the

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rings of contact, which rings cooperate with a current conducting click disk having arms of contact mounted on the drum 25 instead of the contact giver 22. When the drum 25 is being turned one or more arms of contact on the click disk will switch on the current between the rings of contact when the arms are in the intervening space between the teeth 21 and thus give a pulse for each turning step.

This contact giver will only be able to register turning in one direction and the drum 25 must therefore be able to turn only in this direction when the preadjustment is being made. In return the construction is very reliable and is most dependable.

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The function of the pen will described below in some detail.

In fig. 1 the pen is shown in the position to which it is to be adjusted when a new ampoule 5 is to be inserted. The jacket 26 and the drum 25 are moved away from engagement with the case and the pin 19 and the contacts 32 and 30 have registered this taking apart.

As it appears from the arrows in the drawing the piston 6 of the ampoule 5 is being pressed inwards against the piston rod 12, 13 whereby the screw part 13 and the pin 19 are brought to rotate in such a way that the piston rod is shortened. Because of the slide coupling 16 this screwing together takes place very easily and quickly and hardly any pressure is therefore required on the jacket 41 of the ampoule when the ampoule is being inserted into the case by pressing-in until the jacket 41 bears against the foremost end face of the case 9.

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When the ampoule and the in-between piece 4 are in place

the drum 25 and the jacket 26 can be pushed back in place whereby the pin 19 is pressed forwards to the stop-face 18 by the spring-loaded pin 28 and thereby it is made sure that the pin 19 is in place as shown in fig. 2 which therefore indicates the position of the pen when it is ready for being used. The contact 30 has registered this and switched on the current to an electric circuit which will be explained later.

10 Fig. 3 shows the preadjustment position where the jacket 26 has been pulled out and the contact 32 in activated position while the drum 25 is in engagement with the pin 19. After this the preadjustment can take place by turning the drum the desired number of steps which is registered by the sensor 33, whereby the screw part 13 is being screwed outwards to the right in fig. 3 corresponding to the movement of the piston giving the desired dose. The contact 31 has registered that the pin 19 and the stop-ring 20 are screwed out.

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The pen is now preadjusted and ready for the performance of an injection and as shown in fig. 4 this takes place when the jacket 26 is being pressed forwards until the stop-ring 20 bears against the stop-face 18 whereby the piston 6 has concluded its travel and the liquid is ejected through the tube 3 in the form of a hypodermic needle. In order to safeguard the final pressing-in of the pin the pressure pin 28 in the jacket is provided with a spring which yields to the pressing-in of the pin when injection has come to an end. The contacts 31 and 32 have registered this.

Following this a new preadjustment can take place as shown in fig. 3 and be injected as shown in fig. 4.

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When the ampoule 5 is empty or the residual amount is

too small for a new injection, the ampoule has to be replaced by a new ampoule as shown in fig 1.

Next, the electrical system will be described having reference to fig. 8 showing a simple block diagram.

The current supply is performed by a dry element 37 being embedded in the case in a suitable room 14 as indicated in figs. 1, 2 and 7.

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The contact 30 is a switch which switches on the current when the ring of contact 22 is acting upon the contact 30, see fig. 2, and gives current to an electronic control-supervision unit 10 which can be built into the case as shown in fig. 1-4.

This unit 10 is connected to a display 11 being inserted at the outer side of the case as shown in the same figures.

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The function of the individual switches and sensors is as follows.

The contact 30 switches on the current to the control unit 10 when the ring of contact 22 is acting upon the contact 30. The control unit 10 tests the display for some seconds by connecting all the segments of the display, whereafter the control unit and the display enter their initial positions.

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The switch 32 is deactivated when the jacket is open. This is an indication to the control unit that there exists a wish to use the pen. After this the display is lit and the display now shows the remaining quantity in the ampoule and the size of the dose injected in the preceding injection.

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The contact 33 is activated by turning the dosage drum 25 when the jacket 26 is open. For each turn the control unit 10 is coded with a pulse and the preadjusted number of units is shown in the display. In cases in which too much has been preadjusted the dosage drum 25 can be turned back the desired number of units which is likewise registered in the display which therefore gives an exact indication of the preadjusted dose. In cases in which there is preadjusted a dose being larger than the amount left in the ampoule the display will show an alarm by the flashing of all digits in the indication of the remainder 38.

The contact 31 is activated when the injection has come to an end. If this does not take place within a predetermined number of seconds following the commencement of the injection, the display shall show an alarm signal which will continue until the contact is activated and the injection completed.

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This makes it possible to visualize the status of the pen as indicated in fig. 9 that shows an example of the embodiment of the display 11.

The three digits 38 to the left indicate the remainder in the ampoule - in the example shown an ampoule filled with 250 units - in the middle a battery indicator 39 and to the right an indication 40 of the dose amount and furthermore showing how large the dose of the preceding injection was when the jacket has been pulled out.

Finally in figs. 10-17 there are shown examples of showings in the display as it appears from the following summary.

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Fig. 10 shows how the segments appear for some seconds

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in their check-up showing before the functions as such are initiated.

Subsequently, fig. 11 shows that there are 250 units left in the ampoule and that no injection has taken place yet.

Fig. 12 shows that fifteen units have been preadjusted, and in fig. 13 the jacket has been pushed in and the injection initiated.

After this the display will as shown in fig. 14 show a remainder of 235 units and that fifteen units have been injected; this will remain alight for a period of time of approximately one hour in order to mark that within this period of time an injection of the indicated amount has taken place.

If a registration of injected amount and time is required, such data can be stored or displayed in a generally known manner or be recorded in another manner for later use.

Fig. 15 shows an example where the jacket has been opened; this showing is interrupted when the jacket is being closed. If it is in the middle of a progress in time this progress will continue independently of the working of the jacket in order to make it possible to maintain the control of this progress in time.

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In fig. 16 there is again shown a dosage of five units and a remainder of 225 units and, finally, in fig. 17 there is shown a battery error message.

35 It is preferred to give the dry element a time of life that essentially corresponds to the mechanical time of

life of the pen so that it can be taken out of use when the battery no longer has sufficient capacity.

- 5 There are four different error conditions:
 - 1)

If the user orders more insulin than left in the ampoule or cartridge the three digits to the left shall begin to flash. This flash is only a warning for the user and he shall still be able to increase the wanted dose.

2)

If the user has ordered more insulin than left in the ampoule or cartridge and the injection is not completed or fulfilled within 10 seconds after closing the cap the whole display shall begin to flash. This flash is an alarm that tells the user that the cartridge is empty and he has to change the cartridge.

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3)

If the user has ordered a dose and has not ordered more insulin than the quantity left in the cartridge and the injection is not completed or fulfilled within 10 seconds after closing the cap the two digits to the right begin to flash. This flash is an alarm that tells the user that he has not got the wanted dose.

The flash shal continue until the error is removed which 30 means that the "injection fulfilled" switch is activated.

4)

If the user orders a negative dose, i.e. he turns the dose-counter more backwards than forwards, the two digits to the right will begin to flash.

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The two digits flash with negative signs until the wanted dose is positive or zero. The control-unit must not accept closing of cap if the wanted dose is negative.

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CLAIMS

- 1. An injection pen comprising a case in which an ampoule for a liquid can be inserted and from which liquid 5 is given-off through a tube in the form of a hypodermic needle by pressing a piston downwards within the ampoule by means of a motive device comprising a piston rod that is able to be moved axially and consisting of an outer piece which can be displaced axially in the case and is provided internally with a thread into which a screw is 10 screwed, which screw at the end facing away from the piston is provided with a fixed flange with a pin which by turning can preadjust the length of the piston rod and consequently the axial movement of the piston for 15 giving-off a definite amount of liquid, and where the pin is provided with a stop-ring cooperating with a fixed stop-face placed in the case for the limitation of the pressing-in movement of the piston rod, characterized in that a slide copuling (16) is placed on the pin 20 (19) between the flange (15) and the stop-face (18).
 - 2. Injection pen according to claim 1, characterized in that a drum (22, 25) is arranged on the end of the pin (19) facing away from the piston rod (12, 13) the said drum being operated by one or more fingers for turning of the pin (19).
- 3. Injection pen according to claim 2, characterized in that the drum (22, 25) is arranged in a jacket (26) that is able to be displaced axially in the case (17).
 - 4. Injection pen according to claims 2 and 3, characterized in that the drum (22, 25) can be displaced axially in the jacket (26) to engagement with and release from the pin (19) respectively.

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5. Injection pen according to claims 4-6, characterized in that on the drum (25) there is placed a ring of contact (22) which, in the position of engagement of the drum (25) with the pin (19), cooperates with means (21, 23) provided in the case (17) for the perceptible control of the turning movement of the drums (25) which means (21, 23) are made up of projections (23) on the external side of the ring of contact (22) which projections (23) slide past and over evenly distributed teeth (21) in the case (17) during the turning of the drum (25).

6. Injection pen according to claims 1-5, characterized in that at the end-stop (18) an electrical sensor (31) is placed being acted upon by the stop-ring (20) in its advanced position, that in the case (17) partly an electrical contact (30) is provided being acted upon by the ring of contact (22) in its position of engagement with the pin (19) and partly an electrical sensor (33) detecting and/or registering the turning of the drum

(25), and in that in the case (17) an electrical sensor (32) is placed being acted upon by the jacket (26) in the position in which the jacket (26) is pushed together with the rest of the case (9).

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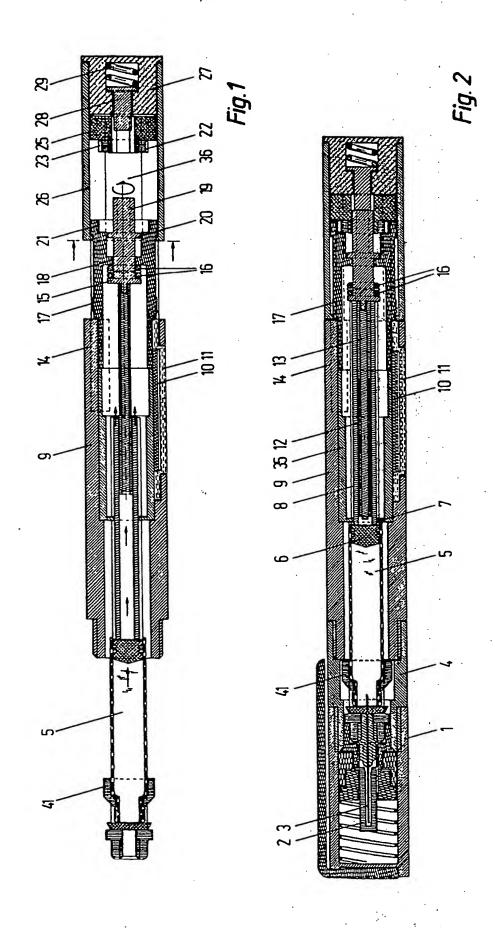
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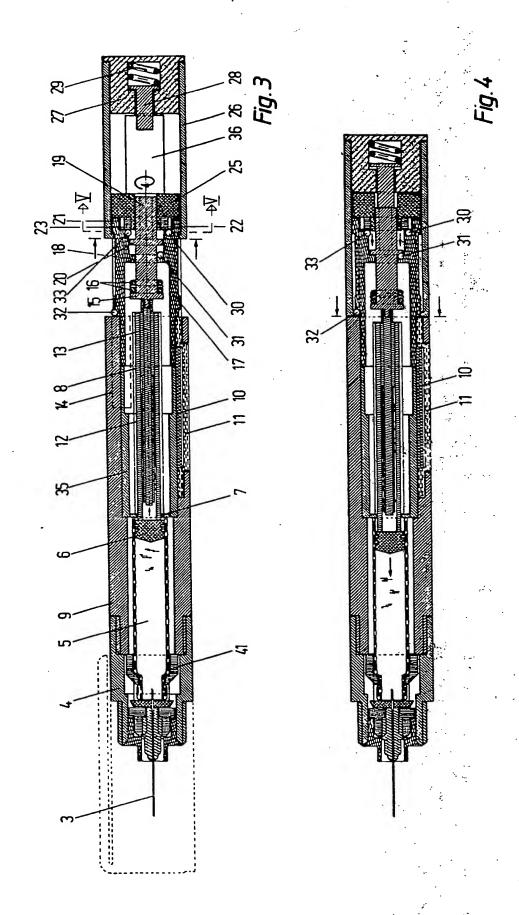
7. Injection pen according to claim 6, characterized in that the ring of contact (22) is provided with forwardly projecting evenly distributed projections (23, 24) which act upon a contact arm (34) on the sensor (33) when the drum (25) is being turned.

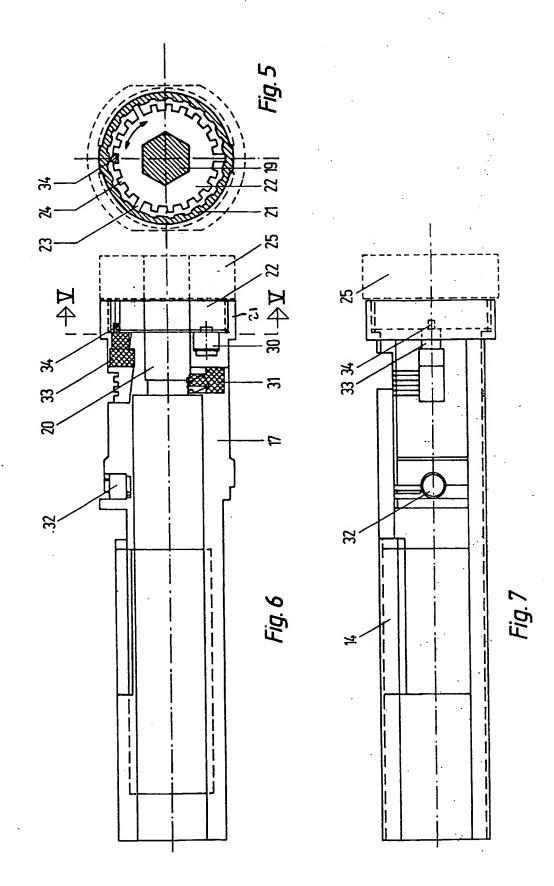
8. Injection pen according to claims 5-7, characterized in that the contact (30) and the sensors (31, 32, 33) are connected electrically to a control unit (10) built into the case (9) and a display (11) for visual supervision or control of the insertion af the ampoule (5, 41),

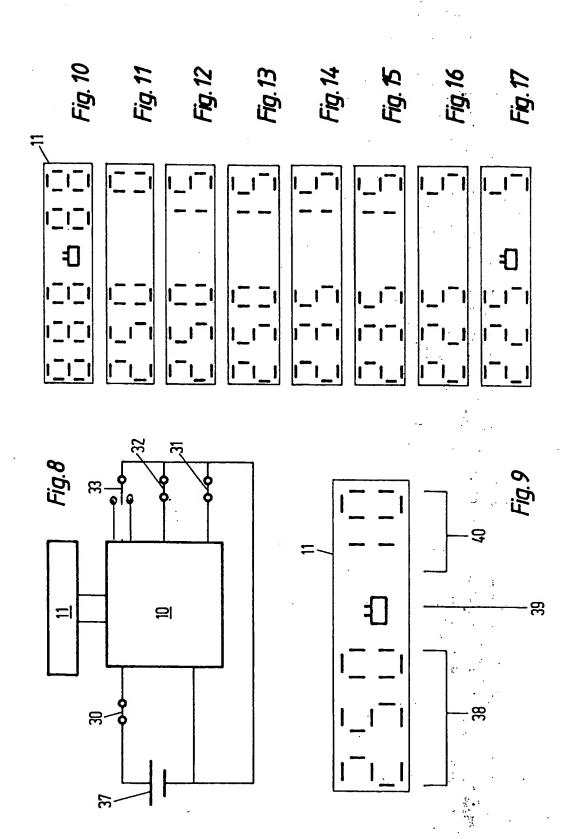
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the remaining amount (38) in the ampoule, the preceding or last injected amount (40) of liquid and the time since this injection, the capacity of the battery, adjusted amount of liquid and the completion of the injection.









INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 90/00038

		N OF SUBJECT MATTER (if several classi		
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